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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert D. TORGERSON et al,
Serial No: 09/209,723
Filed: December 11, 1998
For: COLLAGEN HEMOSTATIC FIBERS
Examiner: V. Bui
Art Unit: 3731

BOX AF
Commissioner for Patents
Washington, D. C. 20231

Sir:

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TECHNOLOGY CENTER R3700

DECLARATION OF STEPHEN N. ELDRIDGE UNDER 37 CFR § 1.132

I, Stephen N. Eldridge, declare as follows:

1. I am a joint inventor of the above-identified patent application and the Research & Development Manager for Hemostasis and Soft Repair Products at Davol, Inc., a subsidiary of C. R. Bard, Inc., which is an assignee of the above-identified patent application. I make this Declaration in support of a Response filed in connection with the above-identified patent application.

2. Collagen is an acidic protein. Accordingly, when collagen is placed in water, the collagen suspension has an acidic pH. This is due, in part, to the acidic nature of the collagen molecule and, in part, to the non-buffering capacity of water.

3. I have prepared suspensions of collagen in water which range in concentration from about 0.85 % collagen (weight/volume) to about 0.95 % collagen (weight/volume). These collagen suspensions in water were prepared in the manner described in the above-identified patent application. More specifically, the slurries were prepared by mixing 700ml of distilled water with 7 gm of dry collagen fiber (Avitene bulk flour). The slurry was hydrated for 2 hours and then homogenized. Homogenized slurry was filtered and tested for pH and the percent collagen (by thermo-gravimetric analysis). These results are listed in Table 1.

U.S.S.N.: 09/209,723

- 2 -

Att Unit: 3731

Table 1:

Date of slurry preparation	Slurry pH	% collagen	Notebook #	Page #
08/04/2000	3.09	.85 (n=2)	N.B. 471	8, 23
08/07/2000	3.04	.95 (n=2)	N.B. 471	9, 10, 24

To test for % collagen in the slurry, a Perkin-Elmer TGA Pyris 1 was used. The material was placed into a sample pan and held at 50°C for 2 minutes, then heated from 5°C to 150°C at 10°C/minute, and held at that temperature for 10 minutes. Copies of the above-referenced notebook pages are attached hereto as Exhibit 1.

4. The pH of the collagen suspensions prepared in accordance paragraph 3 above ranged from pH 3.04 to pH 3.09. These results are consistent with my expectations based on the acidic nature of the collagen molecule itself and the non-buffering capacity of water.

5. I, the undersigned, declare that all statements herein of my own knowledge are true and that all statements made on information and belief are believed to be true. And further, that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of title 18 of the United States code and that such willful false statements may jeopardize the validity of this document and any patent which may issue from the above-identified patent application.

Date

9/4/01

Stephen N. Eldridge

R & D Manager

Hemostasis and Soft Repair Products

Davol, Inc.

Cranston, RI 02920